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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,665	06/08/2001	Paul J. Godowski	P1084R1-1C1	9491
9157	7590	04/19/2004	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			PAK, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,665

Applicant(s)

GODOWSKI ET AL.

Examiner

Michael Pak

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Amendment filed December 23, 2003 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed December 23, 2003, have been fully considered but they are not found persuasive.
4. Claims 34-36 are pending. Claims 1-33 and 37-38 have been cancelled.

Claim Rejections - 35 USC § 112

5. Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-36 recite or encompass the terms "ErbB4", "ErbB3" and "ErbB2" which is ambiguous because it is not clear what is the metes and bounds of each term. Only the name has been provided which can change over time and no structure of the receptor has been provided except by name. It is not clear what structural features separates each of the receptor from the other.

Applicants argue that the ErbB receptors are disclosed in the specification and in the art cited in the specification and is well known to one skilled in the art. However, no structure of the receptor has been provided except by name and metes and bounds are not clear what receptors are encompassed by the terms. For example if the receptors are fusion protein or heteromultimeric receptors then which receptor family does the receptors belong to. Furthermore, Young et al. (US 2004/0048295) disclose heregulin-like factor (HLF) as a specific species of SEQ ID NO:2 and also as fusion proteins which have different names and it is not clear what the HLF receptor will be categorized as since the naming of the protein is not the same as applicant's naming of the protein.

Claim Rejections - 35 USC § 102

6. Claims 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al.(US 2004/0048295) or Young et al. (US 6727077).

Young et al. (US 2004/0048295) is the US Publication and Young et al. (US 6727077) is the divisional of the Publication application. The rejection will refer to the specification of Young et al. (US 2004/0048295).

Young et al. disclose a method of assaying the binding with detectably labeled HLF protein (paragraphs 17-18, 70-71, 136, 185-190, 206, 216, 229, 253, 259). The HLF protein, SEQ ID NO:2, of Young et al. has 100% amino acid sequence identity with the claimed SEQ ID NO:4. Since the HLF protein is identical to the claimed SEQ ID NO:4, the HLF protein would inherently have the function of SEQ ID NO:4.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0507.

Michael D. Pak

Michael Pak
Primary Examiner
Art Unit 1646
31 March 2004